



**Errata to the FDA Briefing Document
Oncologic Drugs Advisory Committee Meeting
March 20, 2012
NDA 22465/S-010
Pazopanib (VOTRIENT[®])
Applicant: GlaxoSmithKline**

1. Table 11, page 17 changed from:

Table 1 Progression-free Survival per IRC Review, ITT Population*

	Placebo (n=123)	Pazopanib (n=246)
Patient Classification, n(%)		
Progressed or died	106 (86)	163 (66)
Censored	17 (14)	83 (34)
Kaplan-Meier Estimate for PFS (months)		
Median (95% CI)	4.6 (4.1, 4.9)	1.6 (1.0, 1.9)
Adjusted hazard ratio (95% CI) ^a	0.35 (0.26, 0.48)	
Stratified log rank p-value ^a	<0.001	

^a Applicant analysis. Confirmed by FDA.

^a Hazard ratio is estimated using the Pike estimator. A hazard ratio <1 indicates a lower risk with pazopanib compared with placebo. The hazard ratio and p-value from the stratified log rank test are adjusted for WHO PS and number of prior lines of systemic treatment for advanced disease.

To:

Table 2 Progression-free Survival per IRC Review, ITT Population*

	Placebo (n=123)	Pazopanib (n=246)
Patient Classification, n(%)		
Progressed or died	106 (86)	163 (66)
Censored	17 (14)	83 (34)
Kaplan-Meier Estimate for PFS (months)		
Median (95% CI)	1.6 (1.0, 1.9)	4.6 (4.1, 4.9)
Adjusted hazard ratio (95% CI) ^a	0.35 (0.26, 0.48)	
Stratified log rank p-value ^a	<0.001	

^a Applicant analysis. Confirmed by FDA.

^a Hazard ratio is estimated using the Pike estimator. A hazard ratio <1 indicates a lower risk with pazopanib compared with placebo. The hazard ratio and p-value from the stratified log rank test are adjusted for WHO PS and number of prior lines of systemic treatment for advanced disease.

2. Page 27, Pneumothorax section changed from

Although all of the patients in the phase 3 study had pulmonary metastases, 3 patients in the phase 2 study did not have evidence of pulmonary metastasis.

To:

Although all of the patients in the phase 3 study had pulmonary metastases, 1 patient in the phase 2 study did not have evidence of pulmonary metastasis.